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June 13, 2001

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on Test Plans for 2,3-dihydro-2, 2-dimethyl-7-benzofuranol and 3-chloro-2-methyl-1-propene

Dear Administrator Whitman:

The following comments on the test plans for 2,3-dihydro-2, 2-dimethyl-7-benzofuranol (7OH) and 3-chloro-2-methyl-1-propene (MAC) are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than nine million Americans.

These test plans submitted by the FMC Corporation blatantly violate the terms and spirit of the original HPV framework and the agreement arrived at by the Environmental Protection Agency, the American Chemistry Council, Environmental Defense, and animal protection representatives. If the EPA's commitment to the terms of the HPV agreement is to have any meaning, the EPA must aggressively and consistently address noncompliance with animal welfare principles. The following five points of the agreement, as outlined in the October 14, 1999, letter to HPV participants are violated by the 2,3-dihydro-2, 2-dimethyl-7-benzofuranol and 3-chloro-2-methyl-1-propene test plans:

> "1. In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach."
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> "5. Participants are encouraged to use *in vitro* genetic toxicity testing to generate any needed genetic toxicity screening data, unless known chemical properties preclude its use."
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> "6. Consistent with the OECD/SIDS program, participants generally should not develop any new dermal toxicity data."
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> "9.(b) [I]individual chemicals (i.e., those HPV chemicals not proposed for testing in a category) that require further testing on animals shall be deferred until November 2001 to allow for non-animal test replacements for some SIDS endpoints."

"10. Companies shall allow 120 days between the posting of test plans and the implementation of any testing plans."

The EPA reiterated its commitment to these principles in October 2000 in letters to all HPV participants and trade associations, signed by Susan Wayland, Charles Auer, and Oscar Hernandez. These letters request "all participants adhere to the principles outlined in this letter, including the deferral of animal testing on individual chemicals until November 2001." The EPA further emphasized its commitment to these principles in the *Federal Register* Notice 65 Fed. Reg. 81686 (December 26, 2000). Given the fact that the EPA has proclaimed its commitment to the minimum animal welfare concerns on several occasions, this test plan should have been immediately rejected under the HPV program and not posted for public comment.

These test plans call for animal testing that is significantly above and beyond the HPV program requirements. The test plan for 7OH calls for acute dermal, *in vivo* genetic, and the combined repeat dose/reproductive/developmental toxicity tests, and the MAC test plan proposes aquatic toxicity tests and the combined repeat dose/reproductive/developmental test. *In vitro* genetic toxicity tests should be used to generate any needed genetic toxicity screening data, unless known chemical properties preclude its use (violation of item 5). Additionally, the test plans also call for a dermal toxicity study, which is also proscribed in the October 14 letter (violation of item 6). Furthermore, the FMC's test plans circumvent the public review process. The FMC Corporation volunteered these chemicals on March 10, 1999, yet did not submit test plans until February 13, 2001, *after the majority of the tests had been completed* (violation of item 10). This company therefore has completely dismissed the importance of the public review process and stakeholder input, and violated not only the animal protection agreements, but also the original framework that the HPV participants agreed to follow, which called for a 90-day comment period between submitting proposed test plans and implementing them.

The most glaring breach of the October 1999 Agreement is that these test plans are for individual chemicals, for which testing is specifically deferred until November 2001 (violation of 9(b)). At that time, additional nonanimal tests may be incorporated into the HPV program. One area in which animal tests are wholly inappropriate and unnecessary is aquatic toxicity. If any aquatic toxicity testing was to be conducted, certainly *in vitro* or QSAR methods should be used instead of fish toxicity tests. *In vitro* tests with the protozoan *Tetrahymena* are frequently used as a measure of aquatic toxicity in ecological risk assessments. We have requested a meeting with the EPA to discuss how to incorporate these nonanimal methods into the HPV program.

The described violations of the October 1999 and October 2000 letters were highlighted in an EPA letter to FMC signed by Oscar Hernandez and dated March 7, 2001, in which the EPA requested specifically that the "FMC consider these concerns and advise the Agency within 30 days of any modifications to its submission." The FMC Corporation did not offer any response to this letter until PCRM followed up on this important matter. It is our understanding that only after discussions with PCRM did FMC agree to drop the dermal toxicity test. Furthermore, FMC staff has stated that they perceived the October 1999 agreement to be "optional." Regrettably, it is our understanding that the EPA has chosen not to follow up with FMC on these important issues, again violating its own October 1999 and October 2000 letters.

The EPA should have rejected these test plans in their entirety due to the blatant violations of the basic principles of protocol development, animal welfare mandates, and October agreement. The EPA must set a good example of its commitment to the original HPV framework and the October 1999 agreement if

it expects companies to also commit to the terms and spirit of the agreement. To date, the EPA has failed abysmally to do so.

I can be reached at 202-686-2210, ext. 302, or by e-mail at <ncardello@pcrm.org>. Correspondence should be sent to my attention at the following address: 5100 Wisconsin Ave., Suite 400, Washington, DC 20016. I look forward to your response on this important matter.

Sincerely,

Nicole Cardello, M.H.S.
Staff Scientist

cc: The Honorable Sherwood Boehlert
The Honorable Ken Calvert
The Honorable Jerry Costello
The Honorable Robert C. Smith
Council on Environmental Quality
Steve Johnson, Assistant Administrator for the Office of Pollution, Prevention, and Toxic Substances
William Walter, Executive Vice President of FMC Corporation